

are not inconsistent with this subpart or with other legal requirements.

(b) Any additional rules will be included in the minutes of the meeting when adopted and in the materials compiled under § 14.33 and will be available for public disclosure under § 14.65(c).

### **Subpart C—Establishment of Advisory Committees**

#### **§ 14.40 Establishment and renewal of advisory committees.**

(a) An advisory committee may be established or renewed whenever it is necessary or appropriate for the committee to hold a public hearing and to review and make recommendations on any matter pending before FDA. Except for committees established by statute, before a committee is established or renewed it must first be approved by the Department pursuant to 45 CFR part 11 and by the General Services Administration.

(b) When an advisory committee is established or renewed, the Commissioner will issue a FEDERAL REGISTER notice certifying that the establishment or renewal is in the public interest and stating the structure, function, and purposes of the committee and, if it is a standing advisory committee, shall amend § 14.100 to add it to the list of standing advisory committees. A notice of establishment will be published at least 15 days before the filing of the advisory committee charter under paragraph (c) of this section. A notice of renewal does not require the 15-day notice.

(c) No committee may meet or take action until its charter is prepared and filed as required by section 9(c) of the Federal Advisory Committee Act. This requirement is to be met by an advisory committee utilized by FDA, even though it is not established by the agency, prior to utilization.

(d) The regulations of the Department cited in paragraph (a) of this section provide that the charter of a parent committee may incorporate information concerning activities of a subgroup. In such instances, a subgroup will not be established as a committee distinct from the parent committee. However, a subgroup will be estab-

lished as a separate committee when the charter of the parent committee does not incorporate the activities of the subgroup, or when the subgroup includes members who are not all drawn from the parent committee.

(e) An advisory committee not required to be established by law will be established or utilized only if it is in the public interest and only if its functions cannot reasonably be performed by other existing advisory committees or by FDA.

(f) An advisory committee must meet the following standards:

(1) Its purpose is clearly defined.

(2) Its membership is balanced fairly in terms of the points of view represented in light of the functions to be performed. Although proportional representation is not required, advisory committee members are selected without regard to race, color, national origin, religion, age, or sex.

(3) It is constituted and utilizes procedures designed to assure that its advice and recommendations are the result of the advisory committee's independent judgment.

(4) Its staff is adequate. The Commissioner designates an Designated Federal Officer and alternate for every advisory committee, who are employees of FDA. The Designated Federal Officer is responsible for all staff support unless other agency employees are designated for this function.

(5) Whenever feasible, or required by statute, it includes representatives of the public interest.

[44 FR 22351, Apr. 13, 1979, as amended at 55 FR 42703, Oct. 23, 1990]

#### **§ 14.55 Termination of advisory committees.**

(a) Except as provided in paragraph (c) of this section, a standing advisory committee is terminated when it is no longer needed, or not later than 2 years after its date of establishment unless it is renewed for an additional 2-year period. A committee may be renewed for as many 2-year periods as the public interest requires. The requirements for establishment of a committee under § 14.40 also apply to its renewal.

(b) FDA will issue a FEDERAL REGISTER notice announcing the reasons for terminating a committee and, if it

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is a standing committee, amending § 14.100 to delete it from the list.

(c) TEPRSSC is a permanent statutory advisory committee established by section 358(f)(1)(A) of the Public Health Service Act, as added by the Radiation Control for Health and Safety Act of 1968, transferred to the FD&C Act (21 U.S.C. 360kk(f)(1)(A)), and is not subject to termination and renewal under paragraph (a) of this section, except that a new charter is prepared and filed at the end of each 2-year period as provided in § 14.40(c). Also, the statutory medical device classification panels established under section 513(b)(1) of the FD&C Act (21 U.S.C. 360c(b)(1)) and part 860, and the statutory medical device good manufacturing practice advisory committees established under section 520(f)(3) of the FD&C Act (21 U.S.C. 360j(f)(3)), are specifically exempted from the normal 2-year duration period.

(d) Color additive advisory committees are required to be established under the circumstances specified in sections 721(b)(5)(C) and (D) of the FD&C Act (21 U.S.C. 379e(b)(5)(C) and (D)). A color additive advisory committee is subject to the termination and renewal requirements of the Federal Advisory Committee Act and of this part.

(e) The Tobacco Products Scientific Advisory Committee is a permanent statutory advisory committee established by section 917 of the Family Smoking Prevention and Tobacco Control Act (21 U.S.C. 387q) (Pub. L. 111–31) and is not subject to termination and renewal under paragraph (a) of this section.

[44 FR 22351, Apr. 13, 1979, as amended at 75 FR 73953, Nov. 30, 2010; 78 FR 17087, Mar. 20, 2013]

### Subpart D—Records of Meetings and Hearings Before Advisory Committees

#### § 14.60 Minutes and reports of advisory committee meetings.

(a) The Designated Federal Officer or other designated agency employee prepares detailed minutes of all advisory committee meetings, except that less detailed minutes may be prepared for open portions of meetings which under

§ 14.61, must be transcribed or recorded by the agency. Their accuracy is approved by the committee and certified by the Chairperson. The approval and certification may be accomplished by mail or by telephone.

(b) The minutes include the following:

(1) The time and place of the meeting.

(2) The members, committee staff, and agency employees present, and the names and affiliations or interests of public participants.

(3) A copy of or reference to all written information made available for consideration by the committee at the proceedings.

(4) A complete and accurate description of matters discussed and conclusions reached. A description is to be kept separately for the following portions of the meeting to facilitate their public disclosure: The open portions specified in § 14.25 (a) and (b), any closed portion during which a presentation is made under § 14.25(c), and any closed deliberative portion under § 14.25(d). The minutes of a closed deliberative portion of a meeting may not refer to members by name, except upon their request, or to data or information described in § 14.75(b). Any inadvertent references that occur are to be deleted before public disclosure.

(5) A copy of or reference to all reports received, issued, or approved by the committee.

(6) The extent to which the meeting was open to the public.

(7) The extent of public participation, including a list of members of the public who presented oral or written statements.

(c) For a meeting that has a closed portion, either (1) the minutes of the closed portion are available for public disclosure under § 14.75(a)(6)(i), or (2) if under § 14.75(a)(6)(ii) they are not promptly available, the Designated Federal Officer or other designated agency employee shall prepare a brief summary of the matters considered in an informative manner to the public, consistent with 5 U.S.C. 552(b).

(d) Where a significant portion of the meeting of a committee is closed, the committee will issue a report at least annually setting forth a summary of